

IN THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application:

Listing of Claims:

1 - 31. (Cancelled).

32. (Previously Presented) The integrated fluid harvesting and analysis device of claim 64, and further comprising a sealed electrical connection to at least one of the sensor (c) and a probe via the first means.

33-50. (Cancelled).

51. (Previously Presented) A method for harvesting interstitial fluid from tissue and analyzing the interstitial fluid, said method comprising the steps of:

(a) porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte;

(b) collecting the sample from the opening,

wherein:

(c) step (b) is enhanced by applying a vacuum to the selected area of the skin;

(d) the sample is collected in an article comprising:

(i) a pad capable of receiving the sample and

(ii) a strap or adhesive tape for holding the pad to the selected area of skin,

(e) the article contains an opening suitable to allow the sample to contact the pad; and

(f) determining the amount of analyte within the sample.

52-63. (Cancelled).

64. (Previously Presented) An integrated fluid harvesting and analysis device, comprising:

(a) a first layer;

(b) a porating element:

(i) for forming at least one opening in tissue;

(ii) disposed on the first layer (a);

(c) a sensor:

(i) positioned in fluid communication with the at least one opening in the tissue;

(ii) responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid;

(d) first means for pneumatically sealing the first layer (a) and the sensor (c) to the surface of the tissue and forming a sealed chamber; and

(e) second means coupled to the first means [(d)] (d) for supplying negative pressure to the sealed chamber.

65-67. (Cancelled)

68. (Previously Presented) A multi-layer assay device comprising:

(a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;

(b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid; and

(c) a substrate layer configured to interface with a processing circuit, wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and facilitates the movement of the biological fluid to the sensor (b); and further wherein said assay device has at least one opening therein through all said layers through which a hole can be made in biological tissue.

69. (Currently Amended) A multi-layer assay device comprising:

(a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;

(b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid;

(c) a substrate layer that is configured to electrically connect to a processing circuit, and

(d) a bottom layer; wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and wherein said assay device has at least one opening therein through all said layers [[in]] through which a hole can be made in biological tissue.

70. (Cancelled)

71. (Previously Presented) A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising:

a. providing a multi-layer integrated device comprising:

(i) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;

(ii) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid;

(iii) a substrate layer configured to interface with a processing circuit, and

(iv) a bottom layer; wherein the receiving layer (i) is located underneath at least a portion of the substrate layer (iii) and wherein said layer (iii) has at least one opening therein;

- b. forming an open hole in biological tissue suitable for extracting a sample of biological fluid suitable for measuring a characteristic of the fluid;
- c. extracting the sample from the unobstructed skin opening and introducing the sample into the integrated device, wherein at least one of the positive and negative pressure is applied to the biological tissue adjacent to the hole in order to enhance the extraction of the sample; and
- d. measuring a characteristic of the biological fluid.

72. (Previously Presented) The method of claim 71 wherein the biological fluid comprises blood.

73. (Previously Presented) The method of claim 71 wherein the biological fluid comprises interstitial fluid.

74-77. (Cancelled)

78. (Previously Presented) A method for performing a diagnostic test utilizing a sample of biological fluid, said method comprising the steps of:

- (a) forming an open hole in an area of skin from which said sample is to be extracted; extracting said sample from said hole in said area of said skin, with the aid of vacuum and stretching of the skin;
- (b) providing a multiple-layer article comprising:
 - i. a layer capable of receiving biological fluid and transporting the biological fluid received by means of a surfactant coated mesh;
 - ii. a layer capable of detecting the presence of analyte or measuring the amount of analyte in biological fluid; and
 - iii. a layer that can be placed in contact with a meter, the meter-contactable layer overlying the biological fluid-transporting layer, said layer (i) capable of transporting biological fluid to said layer (ii);

(d) allowing said extracted sample to be received by said biological fluid-transporting layer and allowing said biological fluid to be transported by said means of a surfactant coated mesh to said layer capable of detecting the presence of analyte or measuring the amount of analyte in biological fluid; and

(e) determining the presence of analyte or measuring the amount of analyte in biological fluid.

79. (Previously Presented) A method for performing a diagnostic test utilizing a sample of biological fluid, said method comprising the steps of:

- (a) forming a hole in an area of skin from which said sample is to be extracted;
- (b) extracting said sample from said hole in said area of said skin, with the aid of vacuum and stretching of the skin;
- (c) providing a multiple-layer article comprising:
 - i. a covering layer having an opening therein;
 - ii. a layer, overlying the covering layer, capable of receiving biological fluid through the opening in the covering layer and transporting biological fluid by means of a surfactant coated mesh;
 - iii. a layer that can be placed in contact with a meter, the meter-contactable layer overlying the biological fluid-transporting layer; and
 - iv. a layer capable of detecting the presence of analyte or measuring the amount of analyte in biological fluid, which layer is disposed between the covering layer and the meter-contactable layer and is capable of receiving biological fluid from the fluid-transporting layer;

(d) allowing said extracted sample to be received by said fluid-transporting layer and allowing said biological fluid to be transported by said means of a surfactant coated mesh to

said layer capable of detecting the presence of analyte or measuring the amount of analyte in biological fluid; and

(e) determining the presence of analyte or measuring the amount of analyte in biological fluid.

80. (Cancelled)

81. (Currently Amended) A multiple-layer element comprising:

(a) a layer capable of receiving blood and transporting the blood received by means of a surfactant coated mesh;

(b) a layer capable of detecting the presence of analyte or measuring the amount of analyte ~~in blood~~ in blood; and

(c) a layer that can be placed in contact with a meter, the meter-contactable layer overlying the blood-transporting layer, said layer (a) capable of transporting blood to said layer (b), wherein said meter-contactable layer has at least one opening therein.

82. (Previously Presented) The article of claim 81, wherein said blood-transporting layer comprises a wick.

83. (Currently Amended) Multiple-layer article comprising:

(a) a covering layer having an opening therein;

(b) a layer, overlying the covering layer, capable of receiving blood through the opening in the covering layer and transporting blood by means of a surfactant coated mesh;

(c) a layer that can be placed in contact with a meter, the meter-contactable layer overlying the blood transporting layer; and

(d) a layer capable of detecting the presence ~~[[or]]~~ of analyte or measuring the amount of analyte in blood, which layer is disposed between the covering layer and the meter-contactable layer and is capable of receiving blood from the blood-transporting layer,

wherein said meter-contactable layer has at least one opening therein.